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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,227	12/03/2003	Nir Dotan	25681-502-P	7497

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,227	DOTAN ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *31-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/4/05;3/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election of Group 1, claims 1-30, in the paper filed 20 October 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 31-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

The disclosure is objected to because of the following informalities: page 18, lines 15, 18, and 26, --cut-off-- should be recited; page 18, line 26, "who" --are-- should be recited. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1-10, 12-24, and 26-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant teaches elevation of antibodies specific for various oligosaccharide structures in patients with inflammatory bowel disease. However, absent further guidance, one would doubt, on its face, that a diagnosis could be made based upon determining the presence of at least one, or several, of the antibodies. In this regard, applicant's own work (WO 2004/015420; see page 3) suggests that detection of a number of the identical antibodies is diagnostic for multiple sclerosis, not Crohn's disease. Moreover, detection of some of the identical antibodies is diagnostic for peripheral neuropathies (see e.g.: Pestronk, US 5,443,952,, col.7, Table II). The art would suggest that even the detection of anti-*Saccharomyces cerevisiae* mannan antibodies (ASCA) would not, by itself, serve to diagnose Crohn's disease (See: Krause et al., Clin. Exp. Rheumatol. 20 (Suppl. 26): S21; Esnault et al., US 7,109,182, col. 7, lines 48-58). For the above reasons and absent further guidance from applicant, one would not be assured of the ability to successfully practice the invention as instantly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, and claims dependent thereupon, "one an" at line 3 is redundant and not clear. These claims also lack a comma at line 6 before "an anti-Dextran".

In claim 2 and claims dependent thereupon, recitations of "the" levels lack antecedent basis.

In claims 5-7, 11, 20, and 21, "detecting" or "is detected" are not consistent with "determining" presence.

In claim 8, "the" presence lacks antecedent basis.

In claims 9 and 10, "the" presence lacks antecedent basis. Moreover, "an...antibodies" is not clear.

In claim 14, "wherein said wherein said" is redundant. Recitation of "said...fluid" lacks antecedent basis because it is believed claim --12-- was intended.

In claim 15 and claims dependent thereupon, "the" isotype lacks antecedent basis.

In claims 16-18, it is not clear what applicant intends as encompassed as a "type antibody."

In claims 20 and 21, "using" is not a valid method step, --with-- is suggested.

In claim 22 and claims dependent thereupon, "said at least one...antibody" lacks antecedent basis.

In claims 23-25, "detecting" is not consistent with "determining" presence.

In claims 26-29, "the" presence lacks antecedent basis.

In claim 29, "the" absence lacks antecedent basis. Moreover, "an...antibodies" is not clear.

In claim 30, "said" antibodies lack antecedent basis. Recitation of "the" absence lacks antecedent basis. The claim also lacks a comma at line 11 before "IgG ASCA".

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 22-30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 22-30 of copending Application No. 10/843,033. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 11-15, 17-19, and 21-28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Main et al. (BMJ 297: 1105, 1988) in light of the instant disclosure, Sendid et al. (Clin. Diagn. Lab. Immunol. 3: 219, 1996), and/or Wakshull et al. (US 6,294,321).

Main et al. detected IgG and IgA antibodies to a crude extract of *Saccharomyces cerevisiae* (ASCA) in the circulation of Crohn's disease (CD), but not ulcerative colitis (UC), patient samples. In light of any of the disclosures of instant specification, Sendid et al., and/or Wakshull et al., the assay of the reference inherently detected antibodies to the glycan epitopes, e.g. β (1-3)-glucans and mannans, present in the extract.

Claims 1-8, 11-20, and 22-28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sendid et al. (Clin. Diagn. Lab. Immunol. 3: 219, 1996) in light of the instant disclosure and/or Wakshull et al. (US 6,294,321).

Sendid et al. detected antibodies to *Saccharomyces cerevisiae* (ASCA) cells in the circulation of Crohn's disease (CD), but not ulcerative colitis (UC), patient samples by immunofluorescence. In light of the disclosures of instant specification and/or Wakshull et al., the assay of the reference inherently detected antibodies to the glycan epitopes, e.g. β (1-3)-glucans and mannans, present in the yeast cells.

Claims 22, 24, and 26-30 are rejected under 35 U.S.C. § 102(b) as being anticipated by Quinton et al. (Gut 42: 788, 1998) in light of Walsh et al. (US 6,218,129).

Quinton et al. discriminated ulcerative colitis (UC) from Crohn's disease (CD) by determinations of anti-neutrophil cytoplasmic autoantibodies (ANCA; positive in UC, negative in CD) and antibodies specific for the oligomannosidic epitopes of *Saccharomyces cerevisiae* (ASCA; positive in CD, negative in UC) in the serum of patients and controls. In light of Walsh

et al., the antiserum used by Quinton et al. (specific for human IgG, IgA, and IgM) detected at least IgG and IgA ASCA.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 and 31-42 of copending Application No. 10/843,033. Although the conflicting claims are not identical, they are not patentably distinct from each other because the referenced copending application and the instant application are claiming common subject matter in the use of overlapping similar or identical individual or combinations of anti-carbohydrate antibody determinations for diagnosis of Crohn's disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-12, and 18-29 of copending Application No. 11/351,185. Although the conflicting claims are not identical, they are not patentably distinct from each other because the referenced copending application and the instant application are claiming common subject matter in the use of overlapping similar or identical individual or combinations of anti-carbohydrate antibody determinations for diagnosis of Crohn's disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-12, and 18-29 of copending Application No. 11/364,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because the referenced copending application and the instant application are claiming common subject matter in the use of overlapping similar or identical individual or combinations of anti-carbohydrate antibody determinations for diagnosis of Crohn's disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLG

James L. Grun, Ph.D.
December 24, 2006

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641
12/28/06